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| | GUDRUN E. | HUCKETT DRAUDT | | GUILL, RUSSELL L | |
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| | GERMANY | | | 2123 | |

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| · | Application No. | Applicant(s) | | | | |
|--|---|--|--|--|--|--|
| | 10/070,347 | ROMANOVYCH ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Russ Guill | 2123 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| Responsive to communication(s) filed on <u>28 February 2002</u>. This action is FINAL. 2b)⊠ This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 15-25 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 15-25 is/are rejected. 7) Claim(s) 15,18 and 21-24 is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on 28 February 2002 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/29/2003. | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other: | (PTO-413) te atent Application (PTO-152) | | | | |

Art Unit: 2123

DETAILED ACTION

1. Claims 1 – 14 were canceled. Claims 15 – 25 were added. Claims 15 – 25 are pending. Claims 15 – 25 have been examined. Claims 15 – 25 have been rejected. Claims 15, 18, 21 – 24 have been objected to.

Claim Objections

- 2. Claim 15 is objected to because of the following informalities: In lines 17 18, the claim recites, "reading the map." Reference to the previous limitation should remain consistent to avoid any possible confusion or antecedent issues. The antecedent appears to be either map or maps. Appropriate correction is required.
- 3. Claim 18 is objected to because of the following informalities: In lines 5 6, the claim recites, "in order determine." The phrase appears to mean, "in order to determine." Appropriate correction is required.
- 4. Claim 21 is objected to because of the following informalities: In line 12, the claim recites, "current line." The phrase appears to mean "current lines." Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

a. Claims 15 – 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 2123

- i. Regarding claim 15, the claim recites in line 8, "the magnetic field induction". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a magnetic field induction". Correction or amendment is required.
- ii. Regarding claim 15, the claim recites in lines 8 9, "the measuring plane". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a measuring plane". Correction or amendment is required.
- iii. Regarding claim 15, the claim recites in line 12, "the measured values". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "measured values". Correction or amendment is required.
- iv. Regarding claim 15, the claim recites in line 12, "the function". The term has insufficient antecedent basis. For the purpose of claim . examination, the phrase is interpreted as "a function". Correction or amendment is required.
- v. Regarding claim 16, the claim recites in line 2, "the map". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a map". Correction or amendment is required.
- vi. Regarding claim 18, the claim recites in line 1, "the fields". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "fields". Correction or amendment is required.
- vii. Regarding claim 18, the claim recites in line 2, "the P-wave". The term has insufficient antecedent basis. For the purpose of claim

Art Unit: 2123

Page 4

examination, the phrase is interpreted as "a P-wave". Correction or amendment is required.

- viii. Regarding claim 18, the claim recites in line 2, "the QRS complex". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a QRS complex". Correction or amendment is required.
- ix. Regarding claim 18, the claim recites in line 3, "the energy generated". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "energy generated". Correction or amendment is required.
- x. Regarding claim 18, the claim recites in line 3, "the excitation". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "excitation". Correction or amendment is required.
- xi. Regarding claim 18, the claim recites in line 4, "the heart". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a heart". Correction or amendment is required.
- xii. Regarding claim 18, the claim recites in line 6, "the degree". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a degree". Correction or amendment is required.
- xiii. Regarding claim 19, the claim recites, "wherein the measured data are subjected automatically pass to different analysis steps". The phrase does not appear to have a meaning. For the purpose of claim examination, the phrase is interpreted as "wherein the measured data

Art Unit: 2123

automatically pass to different analysis steps". Correction or amendment is required.

- xiv. Regarding claim 20, the claim recites in line 5, "the sum". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a sum". Correction or amendment is required.
- xv. Regarding claim 20, the claim recites in line 6, "the magnetic field distribution maps". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "magnetic field distribution maps". Correction or amendment is required.
- xvi. Regarding claim 20, the claim recites in line 8, "the effective dipole characteristics". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "effective dipole characteristics". Correction or amendment is required.
- xvii. Regarding claim 21, the claim recites in line 2, "the alternating". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "an alternating". Correction or amendment is required.
- xviii. Regarding claim 21, the claim recites in line 4, "the direction". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a direction". Correction or amendment is required.
- xix. Regarding claim 21, the claim recites in line 6, "the presence". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a presence". Correction or amendment is required.

Art Unit: 2123

Page 6

xx. Regarding claim 21, the claim recites in line 7, "the repolarization process". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a repolarization process". Correction or amendment is required.

xxi. Regarding claim 21, the claim recites in line 8, "the ratio". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a ratio". Correction or amendment is required.

xxii. Regarding claim 21, the claim recites in line 9, "the standard differentiation". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "standard differentiation". Correction or amendment is required.

xxiii. Regarding claim 21, the claim recites in line 9, "these parameters". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "the maximum negative and maximum positive extremes". Correction or amendment is required. xxiv. Regarding claim 21, the claim recites in line 11, "the effective dipole depth curve". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "an effective dipole depth curve". Correction or amendment is required.

xxv. Regarding claim 21, the claim recites in line 12, "the distribution". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a distribution". Correction or amendment is required.

xxvi. Regarding claim 21, the claim recites in line 14, "the curves". The term has insufficient antecedent basis. For the purpose of claim

Art Unit: 2123

examination, the phrase is interpreted as "curves". Correction or amendment is required.

xxvii. Regarding claim 21, the claim recites in line 17, "the actual repolarization process". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "an actual repolarization process". Correction or amendment is required. xxviii. Regarding claim 22, the claim recites in line 2, "the alternating". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "an alternating". Correction or amendment is required.

xxix. Regarding claim 22, the claim recites in line 4, "the direction". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a direction". Correction or amendment is required.

xxx. Regarding claim 22, the claim recites in lines 4 - 5, "the equivalent current dipole". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "an equivalent current dipole". Correction or amendment is required.

xxxi. Regarding claim 22, the claim recites in line 6, "the presence". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a presence". Correction or amendment is required.

xxxii. Regarding claim 22, the claim recites in line 7, "the depolarization process". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a depolarization process". Correction or amendment is required.

Art Unit: 2123

Page 8

xxxiii. Regarding claim 22, the claim recites in line 9, "the effective dipole depth curve". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "an effective dipole depth curve". Correction or amendment is required.

xxxiv. Regarding claim 22, the claim recites in line 10, "the distribution". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a distribution". Correction or amendment is required.

xxxv. Regarding claim 22, the claim recites in line 11, "the current density vectors". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "current density vectors". Correction or amendment is required.

xxxvi. Regarding claim 22, the claim recites in line 12, "the duration". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a duration". Correction or amendment is required.

xxxvii.Regarding claim 22, the claim recites in line 14, "the curve". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a curve". Correction or amendment is required.

actual <u>the</u> depolarization process". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "an actual depolarization process". Correction or amendment is required. xxxix. Regarding claim 23, the claim recites in line 2, "the alternating". The term has insufficient antecedent basis. For the purpose of claim

Art Unit: 2123

Page 9

examination, the phrase is interpreted as "an alternating". Correction or amendment is required.

- xl. Regarding claim 23, the claim recites in line 4, "the direction". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a direction". Correction or amendment is required.
- xli. Regarding claim 23, the claim recites in line 6, "the presence". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a presence". Correction or amendment is required.
- xlii. Regarding claim 23, the claim recites in lines 7 8, "the repolarization process". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a repolarization process". Correction or amendment is required. xliii. Regarding claim 23, the claim recites in line 10, "the ventricular repolarization process". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a ventricular repolarization process". Correction or amendment is required. xliv. Regarding claim 23, the claim recites in line 12, "the effective dipole depth". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "an effective dipole depth". Correction or amendment is required.
- xlv. Regarding claim 23, the claim recites in line 12, "the J point". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a J point". Correction or amendment is required.

Art Unit: 2123

xlvi. Regarding claim 23, the claim recites in line 13, "the distribution". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a distribution". Correction or amendment is required.

Page 10

xlvii. Regarding claim 23, the claim recites in line 13, "the current lines". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "current lines". Correction or amendment is required.

xlviii. Regarding claim 22, the claim recites in line 1 8, "the duration". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a duration". Correction or amendment is required.

xlix. Regarding claim 23, the claim recites in line 20, "the curves". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "curves". Correction or amendment is required.

- l. Regarding claim 23, the claim recites in line 21, "the ST-T interval". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "an ST-T interval". Correction or amendment is required.
- li. Regarding claim 23, the claim recites in line 22, "the ratios". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "ratios". Correction or amendment is required.
- lii. Regarding claim 23, the claim recites in lines 22 23, "the QRS maximum". The term has insufficient antecedent basis. For the purpose

Art Unit: 2123

of claim examination, the phrase is interpreted as "a QRS maximum". Correction or amendment is required.

- liii. Regarding claim 23, the claim recites in line 24, "the presence". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a presence". Correction or amendment is required.
- liv. Regarding claim 24, the claim recites in line 2, "the alternating". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "an alternating". Correction or amendment is required.
- lv. Regarding claim 24, the claim recites in line 4, "the direction". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a direction". Correction or amendment is required.
- lvi. Regarding claim 24, the claim recites in lines 4 5, "the equivalent current dipoles". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "equivalent current dipoles". Correction or amendment is required.
- lvii. Regarding claim 24, the claim recites in line 6, "the time periods". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "time periods". Correction or amendment is required.
- lviii. Regarding claim 24, the claim recites in lines 6 7, "the effective dipoles". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "effective dipoles". Correction or amendment is required.

Art Unit: 2123

- lix. Regarding claim 24, the claim recites in line 9, "the presence". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a presence". Correction or amendment is required.
- lx. Regarding claim 24, the claim recites in line 10 11, "the depolarization process". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a depolarization process". Correction or amendment is required.
- lxi. Regarding claim 24, the claim recites in line 14, "the distribution". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a distribution". Correction or amendment is required.
- lxii. Regarding claim 24, the claim recites in line 16, "the time period". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a time period". Correction or amendment is required.
- lxiii. Regarding claim 24, the claim recites in line 19, "the duration". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a duration". Correction or amendment is required.
- lxiv. Regarding claim 24, the claim recites in line 23, "the presence". The term has insufficient antecedent basis. For the purpose of claim examination, the phrase is interpreted as "a presence". Correction or amendment is required.
- lxv. Regarding claim 25, the claim recites in lines 1-2, "the considered data". The term has insufficient antecedent basis. For the purpose of

Art Unit: 2123

claim examination, the phrase is interpreted as "considered data". Correction or amendment is required.

Page 13

lxvi. Regarding claim 25, the claim recites in line 3, "a self-learning database". The Examiner does not understand the term. The metes and bounds of the claim cannot be determined. For the purpose of claim examination, the phrase is interpreted as "a database". Correction or amendment is required.

lxvii. **Claim 17** is rejected based on its dependency on its and parent claim which is rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 2123

8. Claims 15 - 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carelli (P. Carelli et al.; "Localization of biological sources with arrays of superconducting gradiometers", 1986, Journal of Applied Physics, Volume 59, Number 2) in view of Tilg (B. Tilg et al.; "Magnetocardiographic Computed Tomography – A Model Study on Minimum-Norm Current Dipole Estimation", September 1994, Computers in Caridology 1994), further in view of Tsukada (U.S. Patent Number 6,230,037).

a. Regarding claim 15:

- b. Carelli appears to teach:
 - i. stating an integral equation of the surface density of the magnetic moments, wherein a right term of the equation represents a second differentiation of the magnetic field induction measured by a gradiometer in the normal direction to the measuring plane $(\partial^2 B/\partial z^2)$ (page 647, section "Comparison in the Solution of the Inverse Problem", second paragraph; Because a second order axial gradiometer measures $(\partial^2 B/\partial z^2)$, the ordinary artisan would have knowingly solved the inverse problem using an integral equation of the surface density of the magnetic moments, wherein a right term of the equation represents a second differentiation of the magnetic field induction);
 - ii. determining analytical expressions for factors of a matrix A which approximates the integral operator of the integral equation and computing this matrix (page 647, section "Comparison in the Solution of the Inverse Problem", second paragraph; In order to solve the inverse problem, an ordinary artisan would have knowingly determined

Art Unit: 2123

analytical expressions for factors of a matrix A which approximates the integral operator of the integral equation and computed the matrix);

iii. interpolating the measured values of the function $y = \partial^2 B/\partial z^2$ in the nodes of a preferably small-dimensioned grid (page 646, section "Direct", first paragraph, and figure 1; and page 647, section "Comparison in the Solution of the Inverse Problem", second paragraph; In order to solve the inverse problem, an ordinary artisan would have knowingly interpolated the measured values of the function $y = \partial^2 B/\partial z^2$ in the nodes of a preferably small-dimensioned grid);

c. Carelli does not specifically teach:

- i. A computer-based method for automatically processing magnetocardiographic data of biomagnetic fields, based on a surface density of magnetic moments (layer of magnetic dipoles) or a function of currents as physical and mathematical models of sources of the biomagnetic field;
- ii. solving according to Tickhonov a linear algebraic equation system Ax=y, wherein x is the surface density of the magnetic moments;
- iii. constructing contour line maps of the surface density of the magnetic moments or a current line map, equivalent to the contour line maps, and reading the map into a storage unit or an output unit.

d. Tilg appears to teach:

i. A computer-based method for automatically processing magnetocardiographic data of biomagnetic fields, based on a surface

Art Unit: 2123

density of magnetic moments (layer of magnetic dipoles) or a function of currents as physical and mathematical models of sources of the biomagnetic field (*page 805, Abstract and Introduction*);

Page 16

ii. solving according to Tickhonov a linear algebraic equation system Ax=y, wherein x is the surface density of the magnetic moments (*page* 805, *Abstract*);

e. Tsukada appears to teach:

- i. constructing contour line maps of the surface density of the magnetic moments or a current line map, equivalent to the contour line maps, and reading the map into a storage unit or an output unit (*figure* 14A).
- f. The motivation to use the art of Tilg with the art of Carelli would have been the benefit recited in Tilg that the iterative method in connection with the Tikhonov method is very effective in searching distributed and focal myocardial activities if the noise level is less than 10% (*page 808, section 4. Discussion, second sentence*).
- g. The motivation to use the art of Tsukada with the art of Carelli would have been the benefits recited in Tsukada that the invention provides biomagnetic field measuring method which can grasp the whole state of a living body portion by using maps which are greatly reduced in number as compared to the maps required in prior art (*column 3, lines 65 67, and column 4, lines 1 2*).
- h. Therefore, as discussed above, it would have been obvious to the ordinary artisan at the time of invention to use the art of Tsukada and the art of Tilg with the art of Carelli to produce the claimed invention.

Art Unit: 2123

i. Regarding claim 16:

- j. Tsukada appears to teach:
 - i. A method according to claim 15, wherein the gradient of the surface density of the magnetic moments is automatically calculated and the map of the current density is constructed and is read into a storage unit or an output unit (*figure 14A*).
- 9. **Claims 17, 19, 20 and 25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Carelli in view of Tilg, further in view of Tsukada as applied to claims 15 16 above, further in view of Suzuki (U.S. Patent Number 6,336,043).
 - a. Carelli as modified by Tilg and Tsukada teaches a method for automatically processing magnetocardiographic data of biomagnetic fields as recited in claims 15 16 above.
 - b. Regarding claim 17:
 - c. Suzuki appears to teach:
 - i. A method according to claim 15, wherein at least selected data are compared according to predetermined criteria automatically with at least one predefined normal value and that, upon deviation of the data from the normal value by a predetermined amount, a signal is generated which can be output on an output device and which signals the deviation (*column* 13, *lines* 1 37).

Art Unit: 2123

d. The motivation to use the art of Suzuki with the art of Carelli as modified by Tilg and Tsukada would have been the benefits recited in Suzuki that the invention provides a biomagnetic field mapping display system which can display an image which changes with time in real time (*column 1, lines 47 - 51*), which would have been recognized as a benefit by the ordinary artisan to improve diagnostics ability.

e. Regarding claim 19:

- f. Suzuki appears to teach:
 - i. A method according to claim 15, wherein the measured data are subjected automatically pass to different analysis steps and wherein the complexity of the analysis increases with each analysis step (*column* 13, *lines* 45 67).

g. Regarding claim 20:

- h. Suzuki appears to teach:
 - i. A method according to claim 19, wherein at least one of the following analysis steps is employed:
 - (1) amplitude-time analysis of different MCG curves;
 - (2) analysis of high-resolution MCG;
 - (3) analysis of the sum of MCG and vector MCG (VMCG);
 - (4) qualitative analysis of the magnetic field distribution maps (figure 31 and column 13, lines 59 61);
 - (5) quantitative analysis of the magnetic field distribution maps; analysis of the effective dipole characteristics;
 - (6) analysis of two-dimensional charge distribution; and
 - (7) analysis of three-dimensional charge distribution.

Art Unit: 2123

i. Regarding claim 25:

j. Suzuki appears to teach:

k. A method according to claim 15, wherein upon comparison of the considered data

with normal values, the considered data are automatically stored in a self-learning

database and, according to predetermined criteria, are employed for a continuous

formation and checking of normal values and tolerable deviations of the normal

values (*column 13, lines 1 - 37*).

1. Therefore, as discussed above, it would have been obvious to the ordinary

artisan at the time of invention to use the art of Suzuki with the art of Carelli as

modified by Tsukada and Tilg to produce the claimed invention.

10. Examiner's Note: Examiner has cited particular columns and line numbers in the

references applied to the claims above for the convenience of the applicant. Although

the specified citations are representative of the teachings of the art and are applied to

specific limitations within the individual claim, other passages and figures may apply

as well. It is respectfully requested from the Applicant in preparing responses, to fully

consider the references in their entirety as potentially teaching all or part of the claimed

invention, as well as the context of the passage as taught by the prior art or disclosed by

the Examiner.

Allowable Subject Matter

Art Unit: 2123

11. **Claims 18 and 21 – 24** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

- 12. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).
- 13. While *Carelli* teaches stating an integral equation of the surface density of the magnetic moments, wherein a right term of the equation represents a second differentiation of the magnetic field induction measured by a gradiometer in the normal direction to the measuring plane ($\partial^2 B/\partial z^2$), and determining analytical expressions for factors of a matrix A which approximates the integral operator of the integral equation and computing this matrix, interpolating the measured values of the function $y = \frac{\partial^2 B}{\partial z^2}$ in the nodes of a preferably small-dimensioned grid, and Tilg teaches a method for automatically processing magnetocardiographic data of biomagnetic fields, and solving according to Tickhonov a linear algebraic equation system Ax=y, wherein x is the surface density of the magnetic moments, and *Tsukada* teaches constructing contour line maps of the surface density of the magnetic moments or a current line map, equivalent to the contour line maps, and reading the map into a storage unit or an output unit, and Suzuki teaches at least selected data are compared according to predetermined criteria automatically with at least one predefined normal value and that, upon deviation of the data from the normal value by a predetermined amount, a signal is generated which can be output on an output device and which signals the deviation, none of these references taken either alone or in combination with the prior art of record teach a method for automatically processing magnetocardiographic data of biomagnetic fields, specifically including:

Art Unit: 2123

- a. Regarding claim 18: "the magnitude of the fields under the P-wave and the QRS complex are calculated, wherein the magnitude of the fields reflects the energy generated during the excitation of the atria and ventricles of the heart, wherein a ratio of these fields is calculated in order to estimate the electrical activity of the atria in comparison to the electrical activity of the ventricles in order determine parameters related to the degree of heart failure"
- b. Regarding claim 21: "estimating the alternating arrangement of maximum positive and negative extreme values in each magnetic field distribution map; estimating the direction of equivalent current dipoles in each map by using the right-hand rule; estimating the presence of additional extreme values in each magnetic field distribution map and duration of their existence during the repolarization process; calculating the ratio of the maximum negative to the maximum positive extremes in each map and of the standard differentiation of these parameters during the method; estimating the effective dipole depth curve in the repolarization; estimating the distribution and alternating arrangement of current line and the directions of current line vectors in each map during the repolarization; estimating the curve of average and maximum current density during repolarization; automatically evaluating ventricular repolarization with respect to conformity of the actual repolarization process in comparison to normal parameters"
- c. Regarding claim 22: "estimating the alternating arrangement of maximum positive and negative extreme values in each magnetic field distribution map; according to the right-hand rule, estimating the direction of the equivalent current dipole in each map; estimating the presence of additional extreme values in each magnetic field distribution map and the duration of their presence during the depolarization process; estimating the effective dipole depth curve during the depolarization; estimating the distribution and alternating arrangement of current lines and the directions of the current density vectors in each map during the

Art Unit: 2123

Page 22

depolarization; estimating the duration of existence of additional current areas during the depolarization process; estimating the curve of average and maximum current density during the depolarization; automatically evaluating conformity of the actual the depolarization process with normal parameters" d. Regarding claim 23: "estimating the alternating arrangement of maximum

- d. Regarding claim 23: "estimating the alternating arrangement of maximum positive and negative extreme values in each magnetic field distribution map; estimating according to the right-hand rule the direction of equivalent current dipoles in each map; estimating the presence of additional extreme values in each magnetic field distribution map and the duration of their existence during the repolarization process; determining the ordinal number of the map beginning at the point in time at which the direction of the equivalent current dipole of the ventricular repolarization became stably normal (oriented to the left and downward); estimating the effective dipole depth at the J point; estimating the distribution and alternating arrangement of the current lines and the directions of current density vectors in each map during the repolarization; determining the ordinal number of the map beginning at the point in time at which the direction of maximum current density vector of the ventricular repolarization became stably normal, i.e., oriented to the left and downward; estimating the duration of existence of additional current areas during repolarization process; estimating the curves of average and maximum current density during the repolarization at the beginning of the ST-T interval; estimating the ratios of maximum and average current densities in the QRS maximum relative to those at T-maximum; automatically evaluating the estimations with respect to the presence and severity of myocardial ischemia"
- e. Regarding claim 24: "estimating the alternating arrangement of maximum positive and negative extreme values in each magnetic field distribution map; estimating according to the right-hand rule the direction of the equivalent

Art Unit: 2123

Page 23

current dipoles in each map; determining the time periods during which the direction of the effective dipoles remains oriented 1. to the right or to the right and downward, 2. to the left and downward, 3. to the right or to the right and upward; estimating the presence of additional extreme values in each magnetic field distribution map and the duration of their existence during the depolarization process; estimating the relative amplitude of the upwardly and downwardly oriented movement of the effective dipoles during the depolarization; estimating the distribution and alternating arrangement of a current line and the directions of current density vectors in each map during the depolarization; determining the time period during which the direction of maximum current density vectors remains oriented 1. to the right or to the right and downward, 2. to the left and downward, 3. to the right or to the right and upward; estimating the duration of existence of additional current areas during the depolarization process; estimating the peak values of the average and maximum current density during the depolarization and the form of the corresponding curves; automatically evaluating the estimations with respect to the presence of myocardial necrosis"

in combination with the remaining elements and features of the claimed invention. It is for these reasons that the Applicant's invention defines over the prior art of record.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

Art Unit: 2123

a. Nenonen, Jukka T.; "Solving the Inverse Problem in Magnetocardiography", 1994, IEEE Engineering in Medicine and Biology, Volume 13, Issue 4; teaches magnetic dipole sources in the inverse problem

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russ Guill whose telephone number is 571-272-7955. The examiner can normally be reached on Monday – Friday 9:30 AM – 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Rodriguez can be reached on 571-272-3753. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application should be directed to the TC2100 Group Receptionist: 571-272-2100.

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Russ Guill Examiner

Art Unit 2123

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